--42. (New) A method of treating chronic fatigue syndrome in a human by administering to the human the pharmaceutical composition of claim 38, so as to thereby treat chronic fatigue syndrome in the human.--

--43. (New) A method of treating chronic fatigue syndrome in a human by administering to the human the pharmaceutical composition of claim 39, so as to thereby treat chronic fatigue syndrome in the human.--

--44. (New) A method of treating multiple sclerosis in a human by administering to the human the pharmaceutical composition of claim 38, so as to thereby treat multiple sclerosis in the human.--

Canceled.

--45. (New) A method of treating multiple sclerosis in a human by administering to the human the pharmaceutical composition of claim 39, so as to thereby treat multiple sclerosis in the human.--

REMARKS

Claims 1-9, 12-24 and 28-31 were pending in the subject application. By this Amendment applicants have canceled claims 1-9, 12-24 and 28-31 without prejudice or disclaimer, and added new claims 32-45. Applicants maintain that the amendments to the claims raise no issue of new matter and that the new claims are fully supported by the specification as originally filed. Specifically,

support for new claim 32 can be found in the specification as originally filed at, *inter alia*, page 6, lines 4-7; and page 5, line 30 to page 31. Support for new claim 33 can be found in the specification as originally filed at, *inter alia*, page 6, lines 4-7; and page 5, line 30 to page 32. Support for new claims 34 and 35 can be found in the specification as originally filed at, *inter alia*, page 6, lines 16 - 17. Support for new claim 36 can be found in the specification as originally filed at, *inter alia*, page 13, line 29. Support for new claim 37 can be found in the specification as originally filed at, *inter alia*, page 13, line 29. Support for new claims 38 and 39 can be found in the specification as originally filed at, *inter alia*, page 6, lines 4-23. Support for new claim 40 can be found in the specification as originally filed at, *inter alia*, page 3, lines 8-12; page 1, lines 20-24; and page 6, lines 4-14. Support for new claim 41 can be found in the specification as originally filed at, *inter alia*, page 3, lines 14-8; page 1, lines 20-24; and page 6, lines 4-14. Support for new claims 42-45 can be found in the specification as originally filed at, *inter alia*, page 7, line 26 to page 8, line 1. Applicants, therefore, respectfully request entry of this Amendment. Upon entry of this Amendment claims 32-45 will be pending and under examination.

Claim Objection

The Examiner stated that the amendment filed [February 19, 2002] is objected to under 35 U.S.C. §132 because it introduces new matter into the disclosure. 35 U.S.C. §132 states that no amendment shall introduce new matter into the disclosure of the invention. The Examiner stated that the added material that is not supported by the original disclosure is as follows: "an antigen-specific" cited

in claims 1 and 2 and that applicant is required to cancel the new matter in the reply to this Office Action.

In response, without conceding the correctness of the Examiner's position and in an effort to expedite prosecution, applicants have canceled claims 1 and 2 without prejudice.

Claim Rejections under 35 U.S.C. §112, Second Paragraph.

The Examiner stated that claims 1-9, 12-24 and 28-31 are still rejected under 35 U.S.C. §112 second paragraph on the similar ground as previous stated in the Office Action mailed 10/19/01. The Examiner stated that regarding to the rejection on applicants failing to particulary point out which specific transfer factor claims 1-2, applicants attempted to overcome the rejection by amending the transfer factor is an antigen-specific transfer factor. The Examiner further stated that therefore, applicants assert that the rejection should be withdrawn because of this amendment. The Examiner stated that applicants' argument is fully considered, however, it is not persuasive because the particular structures of the claimed transfer factor produced by the infection of HSV-6A [HHV-6A] or HSV-6B [HHV-6B] are not defined. The Examiner stated that, furthermore, applicants' argument based on the amendment is also moot because of the new grounds of rejection. The Examiner also stated that applicants are reminded if they wish to claim a particular transfer factor against a particular antigen as a product claim, a precise structure of the transfer factor should be claimed and, therefore, the rejection is maintained and it affects the dependent claims 3-9, 12-24 and 28-31.

In response, without conceding the correctness of the Examiner's

position, applicants have canceled claims 1 and 2 without prejudice.

The Examiner stated that, regarding the rejection of claims 13 - 18, the cited "subject" is not defined. The Examiner stated that applicants argue that the term "subject" can be clearly understood by the one of skill in the art as a mammal, especially as cited in the specification as a human being. The Examiner stated that in response to applicant's argument, it is noted that the features upon which applicant relies (i.e. a human as a subject for the treatment) are not recited in the rejected claim(s). The Examiner further stated that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response, without conceding the correctness of the Examiner's position and in an effort to expedite prosecution, applicants have canceled claims 13 - 18. In addition, applicants note that new claims 36 and 37 recite the term "human".

The Examiner stated that regarding to the rejection of the undefined "abnormality" cited in the claims 16-18 the applicants assert that "abnormality" is a disease, such as multiple sclerosis and chronic fatigue syndrome as cited in the specification. The Examiner stated that in response to applicant's argument, it is noted that the features upon which applicant relies (i.e. multiple sclerosis and chronic fatigue syndrome) are not recited in the rejected claim(s), and although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. (See In re Van Geuns, 988 F.2d 1181, 26

USPQ2d 1057 (Fed. Cir. 1993)).

In response, without conceding the correctness of the Examiner's position and in an effort to expedite prosecution, applicants have hereinabove canceled claims 16-18 without prejudice.

The Examiner stated that regarding to the rejection of claim 24, applicants try to overcome the rejection by amending the claim. The Examiner stated that applicants further argue that the characteristic of the carrier is not a latent characteristic, but rather a subset of carriers. The Examiner stated that the claim is directed to that subset of the carrier, and in response to applicant's argument, the recitation of "capable" should be amended to reflect an ability that the carrier, has because the word "capable" has a meaning of a latent characteristic.

In response, without conceding the correctness of the Examiner's position and in an effort to expedite prosecution, applicants have canceled claim 24 without prejudice.

Claim Rejections under 35 U.S.C. §102

The Examiner stated that claims 1-2, 5-9, 12-13, 17-24 and 28-31 are still rejected under 35 U.S.C. §102(b) over the prior art De Vinci et al. (Biotherapy 1996, Vol. 9, pp. 87-90) on the similar ground described in the previous Office Action. The Examiner stated that applicants argue that De Vinci et al. do not teach the transfer factor (TF) is an antigen specific against the specific species of Human Herpesvirus-6 and methods of using the same. The

Examiner stated that in contrast, applicants' claimed invention is directed to a transfer factor induced by Human Herpesvirus-6A or 6B. The Examiner stated that applicant's argument is respectfully considered, however, it is not found persuasive. The Examiner stated that because the transfer factor taught by De Vinci et al. is produced by the infection of Human Herpesvirus-6, which exhibits the same activity as it is claimed in the instant application. The Examiner stated that there is not a clue to tell that these two transfer factors are structurally and functionally different.

The Examiner stated that applicant's arguments do not comply with 37 C.F.R.§1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the reference cited or the objection made, and further, they do not show how the amendments avoid such references or objections. The Examiner stated that therefore, the rejection is maintained. The Examiner stated that applicants reminded that The Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products.

The Examiner stated that claims 1-2, 5-9, 12-13, 17-24 and 28-31 are still rejected under 35 U.S.C. §102(b) over the prior art Ablashi et al. (Biotherapy 996, Vol. 9, pp. 81-86) on the similar ground described in the previous Office Action. The Examiner stated that applicants argue that Ablashi et al. do not teach the transfer factor (TF) is an antigen specific against the specific species of Human Herpesvirus-6 and method of using the same. The Examiner stated that in contrast, applicant's claimed invention is directed to a transfer factor induced by Human Herpesvirus-6A or 6B.

The Examiner stated that applicants' argument is respectfully

considered, however, it is not found persuasive. The Examiner stated that because the transfer factor taught by Ablashi et al. is produced by the infection of Human Herpesvirus-6, which exhibits the same activity as it is claimed in the instant application. The Examiner stated that there is not clue to tell that these two transfer factors are structurally and functionally different. The Examiner further stated that applicants' arguments do not comply with 37 C.F.R. 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the reference cited or the objection made. The Examiner stated that further, they do not show how the amendments avoid such references or objections, and, therefore, the rejection is maintained. The Examiner stated that applicants are reminded that The Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products.

The Examiner stated that claims 1-2, 5-9, 12-13, 17-24 and 28-31 are still rejected under 35 U.S.C. §102(b) over the prior art Wilson et al. (US Patent No. 4,816,563) on the similar ground described in the previous Office Action. The Examiner stated that applicants argue that Wilson et al. do not teach the transfer factor (TF) is antigen-specific against the specific species of Human Herpesvirus-6 and methods of using the same. The Examiner stated that in contrast, applicant's claimed invention is directed to a transfer factor induced by Human Herpesvirus-6A or 6B. The Examiner stated that applicants' argument is respectfully considered, however, it is not found persuasive. The Examiner stated that because the transfer factor taught by Wilson et al. is produced by the infection of Human Herpesvirus, which exhibits the same activity as it is claimed in the instant application. The Examiner stated that there is not clue to tell that these two

transfer factors are structurally and functionally different. The Examiner stated that applicants' argument do not comply with 37 C.F.R. §1.111(c) because they do not clearly point out the patentable novelty, which he or she thinks the claims present in view of the state of the art disclosed by the reference cited or the objections made. The Examiner stated that further, they do not show how the amendments avoid such references or objections, and, therefore, the rejection is maintained. The Examiner stated that applicants are reminded that The Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products.

In response, without conceding the correctness of the Examiner's position and in an effort to expedite prosecution applicants have canceled claims 1-2, 5-9, 12-13, 17-24 and 28-31. In addition, applicants note that new claims 32-45 are directed to a cell-free fluid of a mammary gland secretion of a human herpesvirus-6A/6B infected lactating mammal. Such a fluid is not taught by De Vinci et al. nor Ablashi et al. nor Wilson et al. In addition, applicants maintain that Wilson et al. teaches a transfer factor for Herpes Simplex Virus, and not Human Herpesvirus-6A or 6B which is a different virus. Accordingly, neither De Vinci et al., Ablashi et al., nor Wilson et al. teach the claimed invention, because the references fail to teach all the elements of the claimed invention.

Claim Rejections under 35 U.S.C. §103

The Examiner stated that claims 1-9, 12,-24, 28-29 and 30-31 are still rejected under 35 U.S.C. §103(a) as being unpatentable over Wilson et al. (Patent Nos. 4,816,563, and 4,610,878), Ablashi et al. (Biotherapy, 1996, Vol. 9, pp.81-86) in view of Challoner et al. (P.N.A.S. 1995, Vol. 92, pp. 7440-7444).

The Examiner Stated that applicants argue that although Wilson et al. (Patent Nos. 4,816,563,4,610,878), Ablashi et al. (Biotherapy, 1996, Vol. 9, pp. 81-86) all teach that the method for extracting the transfer factor (TF) form viral or other infectious agent infected animal and the method for using the TF enriched milk or cellular extract to treat the chronic fatigue syndrome (CFS) and Challoner et al. Suggest to use HHV-6 specific FT for treating multiple sclerosis (MS), it would not be obvious to combine the teachings of Challoner et al. and Ablashi et al. or Wilson. The Examiner stated that in response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed.Cir. 1992). In this case, even applicants acknowledged that Wilson et al. (Patent Nos. 4,816,563, 4,610,878), Ablashi et al. (Biotherapy, 1996, Vol 9, pp. 81-86) all teach that the method for extracting the transfer factor (TF) from viral or other infectious agent infected animal and the method for using the TF enriched milk or cellular extract to treat the chronic fatigue syndrome (CFS) and Challoner et al. suggest to use HHV-6 specific TF for treating multiple sclerosis (MS). The Examiner stated that therefore, the rejection is maintained.

In response, applicants respectfully traverse the Examiner's rejection. Furthermore, applicants point out that, contrary to Examiner's characterization, they have not acknowledged "that Wilson et al. (Patent Nos. 4,816,563, 4,610,878), Ablashi et al. (Biotherapy, 1996, Vol 9, pp. 81-86) all teach that the method for

extracting the transfer factor (TF) from viral or other infectious agent infected animal and the method for using the TF enriched milk or cellular extract to treat the chronic fatigue syndrome (CFS) and Challoner et al. suggest to use HHV-6 specific TF for treating multiple sclerosis (MS)".

However, without conceding the correctness of the Examiner's position and in an effort to expedite prosecution applicants have canceled claims 1-2, 5-9, 12-13, 17-24 and 28-31. Applicants assert that new claims 32-39 are patentable over Wilson et al., Ablashi et al., in view of Challoner et al. because these claims teach a product not taught or suggested by the references. The cited references, at best, provide a general method, but do not teach or suggest the claimed product. However, existence of a general method does not make obvious a heretofor nonexistent product.

With respect to product claims 32-39, applicants point out that the Court of Appeals for the Federal Circuit, whose decisions are binding on the U.S. Patent Office, has clearly stated in *In re Deuel*, 51 F.3d 1552, 1559 (CAFC 1995), copy of which is attached as **Exhibit A**, that "existence of a general method of isolating cDNA or DNA molecules is essentially irrelevant to the question whether the specific molecules <u>themselves</u> would have been obvious...." (emphasis added) In *Deuel*, the Patent Office rejected Deuel's full length DNA claims as obvious over a prior art disclosure of a part of a related protein and disclosure of a general method for cloning and isolating a DNA. The CAFC reversed the rejection stating that the Patent Office's reasoning

> "amounts to speculation and an impermissible hindsight reconstruction of the claimed invention. It also ignores the fact that claims 5 and 7 are limited

> to specific compounds, and any motivation that existed was a general one, to try to obtain a gene that was yet undefined and may have constituted many forms. A general motivation to search for some gene that exists does not necessarily make obvious a specifically-defined gene that is subsequently obtained as a result of that search. More is needed and it is not found...." *Id*, at 1558.

The CAFC further clarified that the Patent Office's "focus on known methods for potentially isolating the claimed DNA molecules is also misplaced because the claims at issue define compounds, not methods." And, that "[A] general incentive does not make obvious a particular result, nor does the existence of techniques by which those efforts can be carried out." *Id* at 1559.

The *Deuel* case merely adds to the well established principle of patent law that the prior art must teach or suggest every element of a claim to support a *prima facie* case of obviousness. *E.g.*, M.P.E.P. § 2142, 2143.03. Without disclosing a cell-free fluid of a mammary gland secretion of an HHV-6A or an HHV-6B infected lactating mammal as claimed by applicants, Wilson et al., Ablashi et al., in view of Challoner et al. cannot support a *prima facie* case of obviousness of the product claims 32-39.

Moreover, the method of treatment claims 40-45 are patentable over Wilson et al., Ablashi et al., in view of Challoner et al. as these references do not teach using a cell-free fluid of a mammary gland secretion of an HHV-6A or an HHV-6B infected lactating mammal, or a lyophilized product thereof, to treat either multiple sclerosis or chronic fatigue syndrome, as claimed by applicants.

In addition, with regard to Multiple Sclerosis (MS), applicants further note that Challoner et al. does not suggest using HHV-6 specific TF for treating MS. In fact Challoner et al. specifically cautions against proposing viruses play a role in the etiology of MS (p 7444, 3rd whole paragraph) going on to state that the observation of HHV-6 and MS is an associative observation and no causal link is shown (p 7444, 4th whole paragraph). Contrary to Examiner's assertion, Challoner et al. therefore does not teach that MS might be treated using transfer factors specific for HHV-6A and HHV-6B. Moreover, taken in light of the controversy in the field as to whether herpetovirodae are involved in MS aetiology at all (as evidenced in Exhibits 2 and 3 of the Amendment submitted by applicants February 19, 2002) one of skill in the art would not have been motivated to combine the references as there is no teaching of HHV-6 causing MS. Thus, the cited references cannot support a *prima facie* case of obviousness of method claims 40-45.

Accordingly, the obviousness rejection is not proper and should be withdrawn.

Claim Rejections under 35 U.S.C. §112, Second Paragraph.

The Examiner stated that claims 1-2 are also rejected in that the metes and bounds of "an antigen specific" are not defined. The Examiner stated that although the claims are interpreted in light of the specification, the specification, however, fails to define which antigen is referred in the claims. The Examiner stated that because HSV-6A and HSV-6B consist of many antigens, the claims should point out which antigen is intended in the said claim. The Examiner stated that claim 30 is unclear in that the metes and bonds of "a mammal" are not defined. The Examiner stated that because there are so many mammals in the art, is killer whale

intended? The Examiner stated that this affects the dependent claim 31.

In response, without conceding the correctness of the Examiner's position and in order to expedite prosecution, applicants have canceled claims 1, 2 and 30 without prejudice. In addition, applicants note that new claims 36 and 37 recite the term "human".

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee, apart from the total enclosed fee of $570.00, including a $200.00 fee for a two-month extension for time and the $370.00 fee set forth in 37 C.F.R. § 1.17(e), is deemed necessary in connection with the filing of this Amendment. If any other fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

Gary J. Gershik 10/2/02

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